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# The First Non-Heart-Beating Organ Donor in Hawaii - Medical and Ethical Considerations

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## Abstract

*The shortage of organ donors remains a major obstacle in transplantation in Hawaii. Some patients die while waiting for a life-saving organ. Across the nation, "marginal" donors, including non-heart-beating donors are used. The authors describe the first successful non-heart-beating organ donor transplant in Hawaii, and include medical and ethical considerations.*

## Introduction

Since the initial kidney transplant in 1969, more than 500 kidneys have been successfully transplanted in Hawaii.<sup>1</sup> This was followed by successes in transplantation of other organs, including the heart, liver, and pancreas.<sup>2,3,4</sup> Many lives have been saved or prolonged because of these medical innovations. However, donor shortage remains a major limiting factor in transplantation. More than 200 patients are waiting for a kidney, liver, heart or pancreas at any given time in Hawaii, and, unfortunately, some of these patients will die while waiting for an organ to become available.

Hawaii consistently has the lowest number of organ donors, based on population, in the U.S.<sup>5</sup> A number of factors may account for this disparity, but one important factor seems to be associated with our high population of Asian-Americans. A focus group study showed that Asian Americans were likely to be uninformed about organ donation, not to discuss organ donation within the family, and to believe that the body should remain whole for the afterlife.<sup>6,7</sup>

In order to increase the number of donors, one approach used successfully elsewhere is to expand the criteria for cadaveric donation. Organs from more "marginal" donors are now accepted, and organs from non-heart-beating donors are used.<sup>8,9,10,11,12</sup> In many other countries, the concept of brain death was never accepted; therefore, all organs have come from non-heart-beating donors.<sup>13,14</sup> In the U. S., all donors were non-heart-beating donors until the early 1970's, when a Harvard University committee first produced criteria for defining brain death. Some organizations continued to use non-heart-beating donors, while others have resumed the use of

non-heart-beating donors within the past 10 years.<sup>16</sup> The use of organs from non-heart beating donors is not a startling new technology, but a return to a previously accepted practice, using current technology to increase the likelihood of recipient survival.<sup>8</sup>

This report documents the first successful use of a non-heart-beating cadaveric organ donor in Hawaii. The case report is followed by a summary of the medical and ethical issues involved in the use of non-heart-beating donors.

## Case Report

A 47 year-old female nearly drowned while scuba diving in January 1996. Her diving companion found her face down in shallow, but rough waters. She suffered cardiopulmonary arrest requiring 20 to 30 minutes of cardiopulmonary resuscitation (CPR) at the scene; was successfully resuscitated and brought to the emergency room. She was intubated but had suffered severe anoxic brain injury with fixed and dilated pupils and no corneal reflexes. She was then transferred to the Intensive Care Unit where she became hypotensive requiring dopamine and levophed support.

Neurologic consultation revealed severe brain injury and initial evaluation was consistent with brain death. A second neurologic evaluation later indicated slight decortication of the right hand, thereby not meeting the clinical criteria for brain death. Nonetheless her overall prognosis was grim and irreversible, with no chance for meaningful recovery.

Her next of kin were informed of her clinical condition and prognosis. The parents felt that the patient would not want her condition to be prolonged in this manner, based on past verbal advanced directives. The patient had always been very active, vital, and altruistic; this was reflected in her work with a volunteer organization in Third World countries prior to her accident. The parents further felt that she would want to donate her organs to help others, if at all possible. If not, then life support should be withdrawn.

Because she was not brain dead, procurement of organs was not possible in the usual manner. She could, however, qualify for organ donation as a "non-heart-beating donor" after withdrawal of support and cardiopulmonary death occurred. This plan was approved by the family, attending physician, and hospital administrators.

Non-heart-beating organ procurement was performed using the University of Pittsburgh protocol.<sup>17</sup> The patient was taken to the operating room (O. R.) and was taken off the ventilator and vasopressors at 2:40 PM. She had no spontaneous respiration and shortly developed ventricular tachycardia followed by asystole at 2:50 p.m.

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She was pronounced dead by her attending physician in the O. R. at 2:52 p.m. Heparin, lasix and mannitol were administered intravenously and external cardiac compression was initiated in an attempt to circulate these drugs. Surgery was initiated and two kidneys were procured and successfully transplanted later at St. Francis Medical Center in Honolulu. The kidneys functioned immediately and are still functioning well after 3 years.

## Discussion

The shortage of donors is a major problem in providing organ transplantation in Hawaii. At any given time more than 200 patients in Hawaii are waiting for a kidney, heart, liver or pancreas, yet on the average, only 12 to 13 cadaveric donors are available each year. This disparity results in some patients dying while on the waiting list. To alleviate this problem, additional sources of organs have been sought, including the use of living donors and "marginal" cadaveric donors.

The strategy of using living donors is not new. In fact, the first kidney transplant successfully performed in 1954 used an identical twin sibling as the donor.<sup>18,19</sup> In many Asian countries where, until recently, brain death was not legally accepted and consent for cadaveric donation is very low, living donors were the only practical source of organs.<sup>20,21</sup> The use of living-related donors (i.e. siblings, parents or children) where there is an immunologic rationale based on HLA matching, has been expanded to living-unrelated donors (i.e. spouses, friends, distant relatives) where the overwhelming rationales are availability and expediency. With living donors, only kidney donations have been practical; partial pancreas and liver donations have been dangerous, and heart donations are impossible.

Cadaveric donors remain a key source of life-saving organs. The "ideal" cadaver donors are young (ages 18 to 55) patients dying from irreversible brain death, but otherwise perfectly healthy with intact cardiopulmonary function that allows perfusion of all organs until the time of organ procurement in the operating room. But these perfect donors are scarce. This has led to the use of less than perfect or "marginal" donors who are older (> 60 years old), younger (< 6 years old), or have systemic illnesses which may affect the transplanted organ (hypertension, hemodynamic instability, mild nephrosclerosis, diabetes, or mild focal infections).<sup>8,22</sup> The use of "marginal" donors includes the non-heart-beating donor (NHBD).

The use of NHBDs is not new.<sup>19</sup> Prior to brain death being universally accepted and legalized in the U.S., NHBDs were the only source of cadaveric organs for transplantation. These were not ideal organs since varying degrees of warm ischemia after cessation of cardiopulmonary function often led to poor organ function.<sup>8</sup> When the diagnosis of brain death became widely accepted, these heart-beating, brain dead cadaveric patients became the ideal standard. However, some programs in the U.S. continued to use these NHBDs selectively when offered the opportunity.

The term "non-heart beating donor" encompasses two different clinical scenarios. The first is the "controlled" NHBD where death can be anticipated, as in terminally ill patients whose family wishes to withdraw futile life support, or who have orders stating "Do Not Resuscitate". The other is the "uncontrolled" NHBD where death is not anticipated, as in trauma victims who die in the Emergency room.<sup>23</sup>

Table 1.— Non-Heart-Beating-Donor Classifications

	<u>Controlled</u>	<u>Uncontrolled</u>
Cause of death	Illness	Trauma
Cardiac arrest	Anticipated	Unplanned
Hemodynamics	Stable	Unstable
Initiation of preservation	Operating room	Intensive care unit or emergency room
Approach	Open	Catheter
Organ recovery	Multiple	Kidneys only
Warm ischemia	Shorter	Longer
Delayed graft function	Lower	Higher

The use of "uncontrolled" NHBDs is not practical, either medically or ethically. Since these patients die suddenly and unexpectedly, the warm ischemia time tends to be prolonged before procedures can be done to cool and preserve the organs. Furthermore, because of the unexpected nature of these deaths, families often are not readily available to provide consent for donation, further prolonging the warm ischemic times.

This leaves "controlled" NHBD organ recovery as the most viable option. In this scenario, the patient has a terminal illness (i.e. irreversible brain damage from anoxia or drowning, that does not meet the strict criteria for brain death) and the family wishes to withdraw futile life-support. (This is a not uncommon scenario occurring daily in our ICU's.) The family wishes to have the opportunity for organ donation, if possible. If there are no obvious contraindications for organ donation (i.e. malignancy, systemic infection, baseline organ-specific illness), after informed consent by the family, the patient is brought to the O. R. The patient is sterilely prepped and draped to facilitate rapid surgery later. The patient is then extubated and all hemodynamic support drugs are stopped. A physician, who cannot be a member of the transplant team, observes for cessation of respiratory function and asystole. Under most protocols the waiting period is 5 minutes from asystole until death is pronounced by the physician, and only then can medications and surgery commence for organ procurement.<sup>17,19</sup>

In some instances, the patient actually does not die, but continues to have labored respiration and cardiac function for a period of time. After about an hour in this deteriorating state, the organs are usually not usable for transplantation, and the patient is then returned to the floor.<sup>17,19</sup>

Using this type of protocol, from 1994 to 1996, a total of 229 kidneys from NHBDs were collected by 30 of the 63 U.S. organ-procurement organizations (range, 1 to 38 kidneys per organization) and transplanted at the 64 U.S. transplantation centers (range, 1 to 31 kidney transplantations per center) that accepted kidneys from NHBDs. This compares to 8718 cadaveric kidneys from donors with heartbeats transplanted by the same 64 centers during the same period.<sup>24</sup> Survival rate at one year was 83 percent for kidney grafts from NHBDs compared with 86 percent for grafts from donors with

heartbeats ( $P=0.04$ ). The survival rates were high for grafts from NHBDs despite the poorer early function of these grafts; 48 percent of the recipients required dialysis within the first week after transplantation, compared with 22 percent of the recipients of grafts from donors with heartbeats. The primary-failure rate from kidneys from NHBDs was 4 percent, as compared with 1 percent from kidneys from donors with heartbeats. The conclusion was that transplantation of kidneys from NHBDs is often successful, and the use of kidneys from such donors could increase the overall supply of cadaveric kidney transplants.<sup>24</sup> Similar studies from the University of Wisconsin also confirmed that extra-renal organs, such as the pancreas and liver, could also be transplanted successfully from NHBDs.<sup>25,26</sup> A recent report from the University of Pittsburgh Medical Center described 8 livers transplanted from controlled NHBDs, all of which functioned immediately.<sup>27</sup>

The ethics of NHBD have been debated extensively in the literature.<sup>19, 8</sup> The principles of beneficence, non-maleficence and autonomy of the potential donor are carefully weighed against the proposed benefits for the potential recipients and society. The principle of beneficence demands that every diagnostic or therapeutic procedure done prior to declaration of death must be for the benefit of the patient's survival, care and comfort. Organ donation takes a distant secondary consideration until death has occurred. Furthermore, the principle of non-maleficence demands that, above all, we must do no harm to the patient. Thus any medications, tests, or procedures used for organ donation, because of their potential, however remote, for pain, discomfort, or physiologic harm, must wait until death is declared. Finally there is the principle of autonomy, where we must preserve the dignity, rights and wishes of the patient and his family. Informed consent is crucial before any invasive procedures for donation can occur. Taken all together, in organ donation this can be summarized as the "dead donor" rule. We must not do anything to hasten the death of a patient. Death must be declared before organ donation can take place.<sup>19</sup>

The following ethical principles were recently summarized in a report on NHBD published by the Institute of Medicine (IOM).<sup>19</sup>

- (1) Our society benefits from enhancing organ donation.
- (2) Organ donors must be dead at organ removal.
- (3) Absolute prohibition of active euthanasia.
- (4) Complete openness about policies and protocols.
- (5) Commitment to informed consent.
- (6) Respect for donor and family wishes.

In our case report, controlled NHBD was performed successfully using standard medical and ethical guidelines. With this initial experience, hopefully more NHBDs can be performed in the near future, thereby providing a potential increase of 25 percent of kidneys for patients in Hawaii.<sup>8</sup> Preliminary protocols for NHBD are currently being drafted by the Organ Donor Center of Hawaii, using the recommendations by the IOM. (See Table 2) After much thought and planning, with public input (including the views of patient and donor families), a written protocol can be further developed and approved by an appropriate local overseeing organization.

Table 2.— Recommendations of the Institute of Medicine for national policy on Non-heart-beating organ donation

1. Written, locally approved non-heart beating donor (NHBD) protocols.
2. Public openness of NHBD protocols.
3. Case by case decisions on anticoagulants and vasodilators.
4. Family consent for pre-mortem cannulation.
5. Conflict of interest safeguards — separate times and personnel for important decisions.
6. Determination of death in controlled NHBDs by cessation of cardiopulmonary function for at least 5 minutes by electrocardiographic and arterial pressure monitoring.
7. Family options (e.g., attendance at life support withdrawal) and financial protection.

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